

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 33887P WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/012875	International filing date (<i>day/month/year</i>) 12.11.2004	Priority date (<i>day/month/year</i>) 12.11.2003
International Patent Classification (IPC) or national classification and IPC . A61 K35/78 A23L1/30 A61 P3/D8 A61 P3/10		
Applicant BIOGHURT BIOGARDE GMBH & CO. KG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012875

Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-21 as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-31 as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012875

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims <u>1-31</u>	YES
		Claims _____	NO
	Inventive step (IS)	Claims <u>1-31</u>	YES
		Claims _____	NO
	Industrial applicability (IA)	Claims <u>1-31</u>	YES
		Claims _____	NO
2.	Citations and explanations (Rule 70.7)		
1.	This report makes reference to the following document:		
D1:	WO 01/10245 A (TOELLE, MARC), 15 February 2001 (2001-02-15)		
	points 2-4: see Box VIII		
5.	Claims 1-31 (interpreted as explained in Box VIII) meet the requirements of PCT Article 33(2) and 33(3) because their subject matter should be considered novel and inventive in relation to the prior art cited in the search report. The reasons therefor are as follows.		
5.1	<u>Novelty:</u>		
	The prior art cited in the search report does not mention the use of distiller's grains fermented with a yoghurt and/or creamery culture, besides yeast, for		
	(i) preventing and/or treating increased blood sugar levels;		
	(ii) reducing body weight;		

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>(iii) preventing and/or treating metabolic syndrome; and</p> <p>(iv) regulating the intestinal flora.</p> <p>5.2 <u>Inventive step:</u></p> <p>Document D1, which is considered to represent the closest prior art, discloses (see, for example, claim 1, in connection with claims 9-11 and page 3, paragraph 2) distiller's grains fermented with a yoghurt and/or creamery culture, in addition to yeast, and their use for producing foodstuffs or dietary supplements. According to D1, the distiller's grains contain little sugar and carbohydrates, and are thus suitable for diabetics.</p> <p>However, D1 does not suggest the possible use of said distiller's grains for preventing and/or treating increased blood sugar levels, for reducing body weight, for preventing and/or treating metabolic syndrome or for regulating the intestinal flora.</p> <p><u>Industrial applicability</u></p> <p>6. Claims 1-31 meet the requirement of PCT Article 33(4) because their subject matter is industrially applicable.</p>

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

2. The claimed subject matter relates to the use of distiller's grains fermented with a yoghurt and/or creamery culture, besides yeast, for producing a composition for
- (a) preventing and/or treating increased blood sugar levels [**claim 1**],
 - (ii) reducing body weight [**claim 7**],
 - (iii) preventing and/or treating metabolic syndrome [**claim 10**], and
 - (iv) regulating the intestinal flora [**claim 28**].

- 2.1 The above-mentioned uses (ii) and (iv) cannot be necessarily attributed to increased blood sugar levels and cannot be *"regarded as a use according to claim 1"*.

The subject matter of the present claims 7 and 28 is thus unclear (**PCT Article 6**). The same is true of the claims which are dependent on the present claims 7 and 28.

3. Owing to the above-mentioned objection, and for the purposes of this report, the present claims 7 and 28 have been interpreted as if they constituted independent claims directed to the *"use of distiller's grains as per claim 1 for preparing a composition for...(the respective use)"*.

4. The uses claimed in claims 7 and 28 for reducing body weight and regulating the intestinal flora,

Box No. VIII **Certain observations on the international application**

respectively, can include both a therapeutic and a non-therapeutic use.

- 4.1 Owing to their formulation (i.e. *"use...for producing a composition for..."*), claims 7 and 28 have been interpreted for the purposes of this report as if they were directed only to a therapeutic use.